
POLICY AND PROCEDURES

OFFICE OF THE CENTER DIRECTOR**CDER Network Of Experts**

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PURPOSE

This MAPP outlines the process for engaging scientific, medical, or clinical organizations to obtain expertise from members within their organizations for the CDER Network of Experts (NoE) program. This document also describes the process by which CDER staff may utilize the FDA NoE program.

BACKGROUND

The purpose of the NoE is to provide CDER staff with rapid access to external scientific, clinical, and medical expertise to supplement existing knowledge and expertise within the Center.

The NoE is designed to be an additional tool for gathering external expertise. The NoE program allows CDER staff to quickly tap into a network of scientific experts within two weeks of defining a scientific question. The NoE should not be used when CDER Staff has a need for policy advice.

The NoE may be used to address scientific questions during a variety of mission-important activities such as pre-market review, post-market surveillance, and product recalls. As issues evolve, the NoE may be used as a tool to provide a more complete view of the scientific landscape.

NoE Access to external expertise could be related to:

- Category A: a topic within the field of Engineering, Science or Medicine or a disease based question.
- Category B: practical experience within a specific approved product or product line or specified medical indication.
- Category C: a topic related to pending submissions for a specific product or group of specific products

The NoE can be used when CDER staff has a need for:

- Rapid access to external scientific, medical, and engineering expertise to address mission-related scientific, clinical or technical questions.
- Further scientific understanding from external sources not available through other mechanisms. This may include access to expertise in emerging fields.
- Information from individual experts.

The NoE is not a replacement for existing mechanisms for obtaining external scientific or clinical expertise, such as advisory committees, special government employees (SGEs), public meetings, workshops, hearings, scientific literature and conferences, or information from other federal employees.

POLICY

- The NoE is governed by a series of written agreements with external organizations. These organizations include academic institutions, professional scientific, engineering, and medical organizations.
- Participating organizations have agreed to rapid recruitment and screening of appropriate Experts upon request.
- Expert scientists, engineers, and clinicians in NoE will not provide policy advice to the Center.

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- Experts in the NoE can provide specific scientific, engineering or medical information, or academic perspective, based on their tangible real-world experience to aid CDER staff in reaching their own informed conclusions.
 - Experts participating in the NoE will not be SGEs. CDER will not use the NoE process for matters that are the subject of Advisory Committee meetings.
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RESPONSIBILITIES

Director Professional Affairs and Stakeholder Engagement (PASES): Appoints CDER NoE Coordinator.

CDER Super Office Director (or designee):

Note: If there is no CDER Super Office Director, the CDER Office Director is responsible for the following items.

- Appoints one or more Office NoE Liaison(s) to work with the CDER Center NoE Coordinator and facilitate Office staff working with the NoE.
- Determines if the NoE mechanism is appropriate for the issue to be researched.
- Approves or disapproves the designation of staff subject matter experts (SMEs) identified by the Office NoE Liaison.
- Clears the Office NoE Liaison's request to use the NoE and the Issue Outline
- Clears questions for the NoE within three business days.

CDER NoE Coordinator:

- Receives, tracks and coordinates requests to utilize the NoE.
- Ensures questions are scientific and necessary for CDER staff to effectively complete their work.
- Reviews and clears the Issue Outline to determine whether the NoE is the appropriate mechanism to respond to the request. Provides alternative mechanism, if needed.
- Coordinates with FDA counterparts on cross-cutting issues.
- Consults with CDER's Office of Regulatory Policy, Division of Information Disclosure Policy to ensure disclosure of information is appropriate.
- Coordinates and initiates contact with the NoE organizations.
- Sends the Issue Outline and Conflict of Interest (COI) paperwork to selected outside organizations with potential NoE Experts.
- Receives signed and dated Curriculum Vitae (CV) or resumes, and COI paperwork the outside organizations.

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- Shares CV or resumes and COI paperwork with Office NoE Liaison.
 - Conducts the NoE meetings, following all applicable rules following the Procedures section.
 - Posts or supervises the posting of meeting summaries to CDER's NoE Intranet page.
 - Maintains the archived information from all NoE activities, as per National Archives Records Administration (NARA) requirements.

Office NoE Liaison, or designee:

- Receives NoE requests from CDER SMEs in the office or Super Office.
- Completes the Issue Outline with CDER SME.
- Seeks approval from NoE Coordinator to use the NoE to discuss the content in the Issue Outline.
- Forwards the following to the Super Office Director, Office Director, or designee, for clearance:
 - Request to use the NoE.
 - The completed Issue Outline
 - The questions.
- After clearance, forwards cleared materials to the CDER Office NOE Coordinator.
- Attends and generates summaries of meetings with NoE Experts. Forwards the summaries to the CDER NoE Coordinator.

CDER Subject Matter Expert (SME)

- Initiates NoE request.
- Works with the Office NoE Liaison, or designee, to complete the Issue Outline.
- Writes the questions for the NoE.
- Communicates with the CDER NoE Coordinator to identify the appropriate organizations for the NoE call.

Executive, Network of Experts organization (or designee):

- Signs a NoE Agreement with FDA.
- Works with PASE to provide the Experts requested.
- Provides CDER staff and the CDER NoE Coordinator the following within five business days of signing the NoE agreement.
 - List of Experts.
 - Resumes, CVs, or a list of publications of each Expert.
 - Completed and signed COI form from each Expert.

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- Facilitates recruitment and identification of appropriate Experts within five business days.
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PROCEDURES

I. NoE Issue Outline Submitted

CDER SME provides a two-page Issue Outline, to his or her Office NoE Liaison. The Office NoE Liaison forwards the document to the CDER Super Office Director, or Office Director, or designee, for approval.

The Issue Outline is designed to collect the following information:

1. A releasable summary of the issue, including releasable background information..
2. A list of proposed questions for the Expert(s).
3. The expertise and experience needed.
4. If the questions pertain to a pending application, deadlines for a response, and proposed timeframes for interactions.
5. The question category: A, B, or C.
6. The need to disclose confidential commercial information (CCI).

II. Acceptance or Rejection of NoE Request

A. Office Clearance

The CDER Office Director, or designee, approves or disapproves of NoE requests within three business days, based on the following criteria:

- Is answering this question essential for completing the staff member's work?
- Does the Issue Outline provide sufficient context to address the question?
- Are the requested fields of expertise or experience appropriate to address the question?
- Is the NoE mechanism appropriate for the issue?
- Are other sources of expertise more appropriate for addressing this question?

B. CDER NoE Clearance

The cleared Issue Outline is forwarded by the Office NoE Liaison to the CDER NoE Coordinator. The CDER NoE Coordinator determines if the NoE is the appropriate mechanism for the requested information based on:

- The nature of the question being asked.
- How quickly the answer is needed.
- Other mechanisms already in place for obtaining the answer.

If the CDER NoE Coordinator decides the NoE process is the appropriated mechanism, he or she:

- Ensures the questions conform to the criteria detailed in this MAPP.

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- Invites CDER staff wishing to listen to the discussion to contact the CDER SME.

III. A Call for Expertise

After the Issue Outline has been cleared by both the CDER Office Director, and the CDER NoE Coordinator, the CDER NoE Coordinator emails the NoE organizations for appropriate Experts. The request includes:

- The Issue Outline.
- The appropriate Gratuitous Service and Conflict of Interest Form.
- A Confidential Disclosure Agreement (CDA), if discussion of proprietary or confidential information is anticipated (Attachment 8).
- A target date for the communication between CDER staff and the Expert(s).
- A clear due date for submitting supporting documentation.

IV. NoE Response to Expertise Call

Network organizations take up to five business days to complete the following:

- Issue an email request for Experts. The request includes the Issue Outline and other documents provided by CDER.
- Ask prospective Experts to forward their CVs or resumes, and required completed forms, to the organization's NoE contact.
- Forward collected information and forms to the CDER NoE Coordinator.

V. Expert Screening and Selection

Potential experts will be screened twice:

1. **Initial screening:** when their organization becomes an FDA NoE organization.
2. **Second screening:** at the time a specific question is posed.

CDER gathers and manages information on actual and potential conflicts. Experts are asked to self-identify potential conflicts of interest.

VI. Setting up the meeting

CDER NoE Coordinator receives the requested information on Experts from the organization within five business days of the call for expertise. The CDER NoE Coordinator forwards the information to the Office NoE Liaison who:

1. Selects one or more Experts. Shares the selection with CDER SME.
2. Contacts selected Experts to schedule either an individual or a group call with up to nine Experts at once.

VII. Expert Consultation Conference Call

Conference calls with NoE participants will be highly structured.

1. The CDER NoE Coordinator (or designee) begins each call by reading the NoE Rules Statement (Attachment 2).
2. Introductions.
3. The CDER NoE Coordinator (or designee) confirms each Expert on the call has completed the screening questions and appropriate clearance paperwork.

4. Each Expert is given agenda time. During this time CDER NoE Coordinator asks one or more specific questions, seeks individual expertise, and allows each Expert to provide his or her scientific viewpoint.
5. If more than one Expert is participating on a call, CDER staff must ensure that no discussions among participants occur, to avoid influencing opinions.
6. A transcription service takes detailed minutes on each call.
7. The CDER SME (or designee) takes minutes on major discussion points of the call.
8. The CDER NoE Coordinator (or designee) circulates the minutes from the call, with any supplementary written materials submitted by the Expert(s), to the Expert(s) and to CDER staff who participated in the teleconference.
9. Experts have five business days to concur with the minutes and forward edits and comments to the CDER NoE Coordinator.

VIII. Post - Expert Consultation Teleconference Meeting

1. Meeting notes are posted on the NoE Intranet page by the CDER NoE Coordinator.
2. Expert consultation materials are archived by the CDER NoE Coordinator. Materials to be Archived include:
 - The Issue Outline.
 - A complete list of names of Experts consulted.
 - Meeting minutes.
 - Any supplementary materials.
3. If the request for expertise was made in reference to a pending application, or is used in connection with other regulatory actions that require administrative records, the meeting minutes may become part of an action package archived in CDER's Document Archiving, Reporting, and Regulatory Tracking System (DARRTS) or Panorama.
4. Certain related records, such as the names of the participating organizations, the names of the individual participating experts, and minutes of the conversations with individual participating experts, may be releasable to the public in response to Freedom of Information Act (FOIA) requests.
5. CDER may proactively release information that is deemed releasable.

IX. Time Limitations.

Completed CDA and COI forms will be considered valid for six (6) months unless a CDER SME requestor indicates that they are needed for longer. In no case shall the CDA and COI forms remain valid for more than nine (9) months. If the services of the Experts are required for longer than nine (9) months, a new screening application will be necessary. Within reason, the CDER SME may contact the identified Expert(s) as often as needed to address scientific, engineering, or medical issue(s) identified in the Issue Outline for as long as the COI and CDA are in effect. Any additional expert meeting within this time period must be documented by the CDER NoE Coordinator.

REFERENCES

1. Freedom of Information Act (FOIA), 1966.
 2. OMB, 2004. Circular A-123, Revised, Management's Responsibility for Internal Control.
 3. FDA, 2011. Center for Devices and Radiological Health, CDRH Network of Experts: Expert Utilization SOP (Draft).
 4. FDA, 2014. Center for Devices and Radiological Health, CDRH Network of Experts: Expert Enrollment SOP (Final).
 5. FDA, 2010. Center for Drug Evaluation and Research, MAPP 4151.8, Equal Voice: Discipline and Organizational Component Collaboration in Scientific and / or Regulatory Decisions.
 6. FDA, 1996. Center for Drug Evaluation and Research, MAPP 6001.1, Special Government Employees Representing Sponsors Before CDER.
 7. FDA, 2008. Office of the Commissioner, Draft Guidance for the Public and FDA Staff on Convening Advisory Committee Meetings.
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DEFINITIONS

Sponsor: The New Drug Application (NDA) or Biologics License Application (BLA) applicant or the Investigational New Drug Application (IND) sponsor.

Commercial Confidential Information (CCI): Valuable data or information which is used in a business and is of such type that it is customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the entity to whom it belongs.

Conflict of Interest: Because activities or relationships with other persons or organizations, a person is unable or potentially unable to render impartial assistance or advice to the Government, that the person's objectivity in performing the contract is or might be otherwise impaired, or that the person has or might acquire an unfair competitive advantage.

Confidential Disclosure Agreement (CDA): A legal contract that governs the exchange of proprietary or confidential commercial information.

The Gratuitous Service and Conflict of Interest form: A form to be completed by the NoE Expert, disclosing any known or potential conflicts of interest. This form also acknowledges the expert agrees to provide his or her services without compensation.

Issue Outline: A formal outline describing the issue that CDER is interested in receiving feedback on from NoE Experts. See attachment 1.

Network of Experts Organization (NoE): A professional scientific, medical, or academic organization with a signed NoE Agreement with FDA. As part of the NoE Agreement, the organization agrees to identify the Expert(s) and present the names of prospective Experts to the CDER NoE Coordinator, or designee.

Network of Experts Expert: A person who is a member of a participating NoE professional scientific, medical, or academic organization or institution and who agrees to provide feedback to CDER on the specified Issue Outline.

Special Government Employees (SGEs): A person appointed on a full-time, part-time, or intermittent basis to serve with or without compensation for not more than 130 days during any period of 365 consecutive days.

CDER Subject Matter Expert (SME): Reviewer, Project Specialist or Project Manager, or Consumer Safety Officer who identifies the issue and requests to use the NoE.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

ATTACHMENT 1: Issue Outline Template

1. What is the scientific issue and the reason for seeking input from the Network of Experts? Include a description of the issue. An abbreviated form of this summary will be included in the Network of Experts external package. We recommend separating releasable information from non-releasable.
2. What questions are you asking the experts?
3. What type of expertise and/or experience is needed? Are there alternative areas of expertise that would be helpful? Are there specific Network of Experts organizations or members/experts of the organization you would like to request?
4. Does the issue area/question relate to a pending application? If so, provide information on the application and the status of any relevant PDUFA, GDUFA, and BSUFA deadlines. When is the information needed?
5. Will the communication with the expert(s) include discussion of any non-public information? If the discussion could include any non-public information inform the Network of Experts coordinator so he/she can consult with CDER's Office of Regulatory Policy, Division of Information Disclosure Policy to ensure that the disclosure of such information is appropriate and that all participants complete a Confidential Disclosure Agreement (CDA). Any information related to a pending submission, including its existence, can be considered non-public information. No non-public information will be shared with Experts without the explicit consent of the owner of the information, such as the sponsor, applicant, or FDA
6. In which of the following three categories does this issue belong?

Category A: Topic within a field of Engineering, Science, or Medicine or a Disease-Based Question: examples include current state of knowledge in congenital heart disease, latest trends in pharmacogenomics, current technical limitations in disease modeling, latest advances in proteomics

Category B: Practical experience with a specific approved product or product line or specific medical indication: examples include current best practices for cardiovascular imaging, current practice guidelines for using HbA1C tests for diagnosis of diabetes and tyrosine kinase inhibitor therapy, approved risk evaluation and mitigation strategies (REMS), experiences with percutaneous heart valves (may include specific questions related to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable).

Category C: Topic related to pending submissions for a specific product or group of specific products: examples include questions regarding an unapproved product used in a clinical study that is currently under review by the Agency in an active IND or a pending NDA/BLA.[these examples sound like they need an AC, or at least an SGE]

ATTACHMENT 2: Network of Experts Rules Statement

The CDER Network of Experts (NoE) is intended to provide a setting for an informal exchange of scientific expertise.

- Experts are expected to disclose any potential conflicts of interests they may have.
- Experts are asked to confine their responses to answers that represent their scientific or clinical opinion based on experience. They are not asked to provide policy advice or unfounded opinions.
- We want to hear each Expert's point of view. Experts are expected to give robust answers to the questions posed, as individuals.
- Records related to the NoE and NoE conversations, including information discussed here today and the names of participating Experts, may be released to the public by FDA. An Expert should not be doing this for any personal gain or publicity, but rather to voluntarily provide expertise. The participation or involvement of the expert in a Network of Experts call is not an endorsement by FDA or HHS. If for any reason you believe you are unable to comply with these ground rules please let the NoE Coordinator know and remove yourself from the discussion."

ATTACHMENT 3: NoE Post Call Survey

NoE Category:

CDER Requesting Office:

CDER Contact Person:

Organization:

Number and Names of Experts Contacted:

Date of Call(s):

Survey:

Feel free to include any additional information that would help answer the following questions:

- What worked well?
- What didn't work well?
- What can be changed to make the process better?

Process and Logistics:

- 1) How can the NoE process be better clarified in advance to the Center?
- 2) Did the organization provide a timely response (within 7 days)?
- 3) Did the organization provide a list of experts that you needed?
- 4) Did the organization provide resumes and completed Gratuitous Services/Cs for all the experts?
- 5) Did the experts adhere to the rules/guidelines of the NoE call?

Quality:

- 6) Did the experts provide the input you needed to allow you to make a more informed decision?
- 7) Would you use the NoE process again and/or recommend it to your colleagues?

Additional comments:

ATTACHMENT 4: Network of Experts Confidential Disclosure Agreement

This Agreement is made by and between the Food and Drug Administration (“FDA”), an agency of the United States Government, and the undersigned individual who has been referred to FDA by the Organization, through peer identification, as an expert (“Expert”). Collectively or individually, FDA and the Expert shall also be referred to as “Parties” or “Party,” respectively.

WHEREAS, FDA has certain confidential information relating to the (insert area of research and clinical studies) (“Confidential Information”); and

WHEREAS, Expert has a professional interest in the subject matter of the Confidential Information and has agreed to provide his or her individual scientific expertise as described in the attached document, wherein Expert will review (insert list of specific documents to be considered) and discuss with FDA (insert scope of requested input, including answers to specific questions posed by FDA);

NOW, THEREFORE, in consideration of the foregoing, and intending to be legally bound hereby, the Parties hereto agree as follows:

1. FDA shall disclose and transmit Confidential Information to Expert.
2. Expert agrees to accept Confidential Information and employ all reasonable efforts to maintain Confidential Information of FDA secret and confidential, such efforts to be no less than the degree of care employed by Expert to preserve and safeguard its own confidential information. Confidential Information shall not be disclosed, revealed, or given to anyone by Expert except FDA employees.
3. Expert agrees to protect such Confidential Information in accordance with 21 U.S.C. § 331(j), 21 U.S.C. § 360(j), 21 U.S.C. § 379, 18 U.S.C. 1905, and other pertinent laws and regulations governing the confidentiality of non-public information.
4. FDA hereby acknowledges that Expert shall not incur any liability merely for receiving Confidential Information; however, Expert agrees that they will not use Confidential Information for any purpose except as set forth herein.
5. Expert’s obligations under Paragraphs 2 and 3 above shall not extend to any part of Confidential Information of FDA:
 - a. that can be demonstrated to have been in the public domain or publicly known at the time of disclosure; or
 - b. that can be demonstrated to have been in Expert’s possession or that can be demonstrated to have been readily available to Expert from another source prior to the disclosure; or
 - c. that becomes part of the public domain or publicly known by publication

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- or otherwise, not due to any unauthorized act by Expert; or
 - d. that can be demonstrated as independently developed or acquired by Expert without reference to or reliance upon such Confidential Information; or
 - e. that is required to be disclosed by law.
 - 6. The effective date of this Agreement is (insert date). All information to be deemed confidential under this Agreement shall be clearly marked "CONFIDENTIAL" by FDA. Any Confidential Information which is orally disclosed must be reduced to writing and marked "CONFIDENTIAL" by FDA and such notice must be provided to Expert within thirty (30) days of such disclosure. **Notwithstanding** the foregoing, the Expert shall treat as Confidential information received from FDA.
 - 7. It is understood that nothing herein shall be deemed to constitute, by implication or otherwise, the grant to Expert of any license or other rights under any patent, patent application or other intellectual property right or interest belonging to FDA.
 - 8. It is understood and agreed by both parties, that each represents and warrants to the other Party, that the official signing this Agreement on behalf of the Party has authority to do so.
 - 9. The illegality or invalidity of any provision of this Agreement shall not impair, affect or invalidate the other provisions of this Agreement.
 - 10. The construction, validity, performance and effect of this Agreement shall be governed by Federal law, as applied by the Federal Courts in the District of Columbia.

ATTACHMENT 5: Gratuitous Service and Conflict of Interest Forms

The writable PDF Gratuitous Service and Conflict of Interest Forms are attached to this MAPP. Click the paperclip icon, called “Attachments: View file attachments,” on the left side of this PDF document. Then select the category form you need. The categories are as follows:

- **Category A:** For general questions about science, medicine, or public health.
- **Category B:** For questions about an approved product of product line or specific medical indication.
- **Category C:** For questions about pending submissions for a specific product of products.

Export file data: You can save the information from any of the three attachments as a data file in another file format.